PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

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PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Rule 71.1)

Date of mailing *(day/month/year)*	28.02.2001
Applicant's or agent's file reference: P097	**IMPORTANT NOTIFICATION**

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/GB99/04027	01/12/1999	01/12/1998

Applicant
ABERDEEN UNIVERSITY et al.

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.

2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.

3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

Name and mailing address of the IPEA/	Authorized officer
European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Hingel, W Tel.+49 89 2399-8717

Form PCT/IPEA/416 (July 1992)

PATENT COOPERATION TREATY

REC'D 02 MAR 2001

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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
P097		
International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/GB99/04027	01/12/1999	01/12/1998
International Patent Classification (IPC) or national classification and IPC C07K14/705		
Applicant ABERDEEN UNIVERSITY et al.		

1. This International preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 16 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the report
   - II ☐ Priority
   - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations suporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☒ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
30/06/2000	28.02.2001
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer Stolz, B Telephone No. +49 89 2399 8416

Form PCT/IPEA/409 (cover sheet) (January 1994)

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/GB99/04027

I. Basis of the report

1. This report has been drawn on the basis of *(substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments (Rules 70.16 and 70.17).)*:
Description, pages:

1-26 as originally filed

Claims, No.:

1-14 as received on 30/01/2001 with letter of 30/01/2001

Drawings, sheets:

1/6-6/6 as originally filed

Sequence listing part of the description, pages:

1-13, as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☒ furnished subsequently to this Authority in written form.
- ☒ furnished subsequently to this Authority in computer readable form.
- ☒ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☒ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-12, 14
	No:	Claims	13
Inventive step (IS)	Yes:	Claims	1-7, 10-12, 14
	No:	Claims	8, 9, 13
Industrial applicability (IA)	Yes:	Claims	1-14
	No:	Claims	

2. Citations and explanations
   see separate sheet

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:
see separate sheet

1. Reasoned statement

1.1. The application describes peptides derived from Rhesus D and Cc/Ee antigens. The peptides are useful in the prevention of alloimmunization and in the suppression of immun responses to alloantigens.

1.2. The amended set of claims meets the requirements of Art. 34(2)(b) PCT.

1.3. Novelty (Art. 33(2) PCT)

Claim 13 lacks novelty over Barker et al., 1997 (D1). Table 3 of this document provides a list of peptides which coincides with the list of presently claimed peptides. The peptides described in D1 are structurally indistinguishable from the claimed peptides and intrinsically possess tolerising properties when used in the context of the present application. As the claim is directed to the peptides per se, it lacks novelty over D1.

The pharmaceutical compositions according to claims 1 to 11, and the methods of claims 12 and 14 have not been previously described, and are therefore novel.

1.4. Inventive step (Art. 33(3) PCT)

The prior art, D1 and Stott et al., 1998, (D2), respectively, describe the use of the indicated peptides in order to identify Rhesus derived epitopes playing a role in Autoimmune Hemolytic Anemia, and in eliciting immune responses to Rhesus D antigens. D2 finishes by briefly mentioning immuno therapy as a potential approach to the prevention of hemolytic disease of the newborn. However, in light of D2, generally teaching antigenicity of the indicated peptides, the person of skill would not have expected the same peptides to be useful in immune suppression. Therefore, claims 1 to 7 and 12 are considered to be inventive.

The method of claim 14 cannot be derived from the cited prior art in an obvious way.

Claims 8 and 9 are directed to pharmaceutical compositions comprising a given

peptide fragment in a pharmacologically effective vehicle. D2 described RhD derived peptides 2, 12, 12a, 15a, 18a, and 28 as being effective in eliciting an immune response in donors. At least peptides 2, 12, and 28 have been defined in D1. Thus, the use of these peptides for the preparation of pharmaceutical compositions for the generation of an immune response in donors is immediately obvious to the person of skill. Such compositions are indistinguishable from the compositions of claims 8 and 9. Therefore, claims 8 and 9 lack inventive step.

2. Certain observations

2.1. Claim 1 refers to analogues and derivatives of unspecified peptides. The terms "analogue" and "derivative" are open to interpretation and render the scope of the claims unclear. Furthermore, the description does not disclose any such derivative or analogue.

2.2. In view of D2, claims 1 and 8 merely define the goal to be achieved.

2.3. The nature of claims 4 and 10 is unclear (process or product?) due to the statement "when alloimmunization has occurred".

CLAIMS:-

1. A pharmaceutical composition for the prevention of alloimmunisation of a subject or the immunosuppression of a response elicited by alloimmunisation of a subject by tolerisation, said composition comprising an immunologically effective epitope of a rhesus protein or an immunologically active analogue or derivative thereof.

2. A pharmaceutical composition according to claim 1 wherein the rhesus protein is either RhD, RhC, Rhc, RhE or Rhe protein.

3. A pharmaceutical composition according to claim 2 comprising an epitope selected from at least one of SEQ ID numbers 2, 5, 6, 11, 12, 14, 28, 29, 31, 38, 39, 44, 47, 50, 51, 66, 75, 77, 78, 79, 81 and 84 hereinbefore set forth.

4. A pharmaceutical composition according to either claims 2 or 3 wherein the epitope is either SEQ ID number 79 when alloimmunisation has occurred.

5. A pharmaceutical composition according to any preceding claim wherein the epitope or immunoreactive derivative is synthesised.

6. The use in the manufacture of a medicament for the tolerisation of a patient who may become alloimmunised or for the immunosuppression of an alloimmunised patient comprising an epitope selected from a RhD, RhC, Rhc, RhE or Rhe protein or selected from at least one of SEQ ID numbers 2, 5, 6, 11, 12, 14, 28, 29, 31, 38, 39, 44, 47, 50, 51, 66, 75, 77, 78, 79, 81 and 84 hereinbefore set forth, and a pharmaceutically acceptable vehicle therefor.

7. The use according to claim 6 wherein the vehicle is adapted for transdermal or transmucosal administration.

8. A pharmaceutical composition comprising a tolerising peptide fragment disposed in a pharmacologically effective vehicle, said vehicle being adapted for injection, oral, rectal, topical or spray-uptake administration to the subject wherein the peptide fragment is an epitope of either a RhD, RhC, Rhc, RhE or Rhe protein.

9. A pharmaceutical composition according to claim 8, wherein the peptide fragment is selected from at least one of a SEQ ID numbers 2, 5, 6, 11, 12, 14, 28, 29, 31, 38, 39, 44, 47, 50, 51, 66, 75, 77, 78, 79, 81 and 84 hereinbefore set forth.

10. A pharmaceutical composition according to either claim 8 or 9 wherein the fragment is either SEQ ID number 79 when alloimmunisation has occurred.

11. A pharmaceutical composition according to any of claims 8 to 10 wherein the pharmaceutically acceptable vehicle is adapted for transdermal or transmucosal administration or wherein said vehicle is a formulation with an enteric coating for oral administration.

12. A method of tolerising a subject which comprises administering tc said subject a pharmaceutical composition according to any one of claims 8 to 11.

13. A tolerising epitope from a RhD, RhC, Rhc, RhE or Rhe protein selected from at least one of SEQ ID numbers 2, 5, 6, 11, 12, 14, 28, 29, 31, 38, 39, 44, 47, 50, 51, 66, 75, 77, 78, 79, 81 and 84 hereinbefore set forth.

14. A method for determining effect of one or more epitopes from a rhesus protein on a human lymphocyte, *in vitro*, comprising:-

a) stimulating the lymphocyte with one or more epitope/peptide of a rhesus protein;

b) between 4 and 7 days later resuspending the cultures and transferring aliquots into plates prepared in the following manner;

c) coating each well in the plate with monoclonal anti-cytokine capture antibody;

d) washing the plate at least once with Hanks Buffered Salt Solution (HBSS);

e) blocking any non-specific binding using an appropriate solution;

f) incubating the plates with the lymphocyte culture for 12-36 hours at 30-40°C in an atmosphere of substantially 5% CO_2 and substantially 95% air;

g) washing the plates at least once with Tween/PBS;

h) introducing an appropriate biotinylated monoclonal detection antibody to each well and incubating for 30-60 mins at room temperature;

i) washing the plates at least once with Tween/PBS;

j) introducing of ExtrAvidin-alkaline phosphatase conjugate and incubating for 15-45mins;

k) washing the plates at least once with Tween/PBS;

l) developing the plates with 50-150µl per well of p-nitrophenyl phosphate in 0.05M carbonate alkaline buffer pH9.6 added to each well;

m) reading the absorbence at 405nm.

SEQUENCE LISTING

<110> Aberdeen University
The Common Servics Agency For The Scottish Health

<120> ALLO- AND AUTO-REACTIVE T-CELL EPITOPES

<130> P097

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<141> 1999-12-01

<150> 9826378.3
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<160> 152

<170> PatentIn Ver. 2.1

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